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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,105	10/30/2003	Jerome B. Zeldis	9516-073-999	1860

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,105	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *3,4,6-8,10-21,24,25 and 35-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,9,22,23 and 26-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's remarks filed on 6/15/2007. Claim(s) 1-37 are pending. Examiner acknowledges Applicant's request to change the group election to II in accordance with the species election. Claim(s) 3-4, 10, 12-21, 24-25, 35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim(s) 5-8, 11 are withdrawn from further consideration as being drawn to a non-elected species. Applicant's election **without traverse** of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 1-2, 5, 9, 22-23, 26-34 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 9, 22-23, 26-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the treatment of MD in a patient, does not reasonably provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of treating and preventing MD in a patient.

(2) State of the Prior Art: The state of the art regarding treating MD is relatively high, however the state of the art for the prevention of MD is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention and treatment of MD in a patient.

(4) Guidance of the Specification: The guidance of the specification as to the prevention of MD is completely lacking. The specification discloses preventing the onset of MD. However, the specification fails to mention how one is able to determine whether the onset of MD in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the

specification fails to mention the complete prevention or cessation of MD once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating and preventing MD. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent MD, nor does the prior art reveal any type of prevention associated with MD.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent MD. Moreover, one is unable to determine whether a subject will ever develop a MD should this subject be administered a JNK inhibitor of formula I.

(7) Working Examples: The specification does not give any data for the prevention of MD in a patient.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of MD. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claims 1, 22, 26-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of MD with a JNK inhibitor of formula I, does not reasonably provide enablement for all JNK inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to the treatment of MD with any and all JNK inhibitors.

(2) State of the Prior Art: The state of the art regarding JNK inhibitors is relatively modest.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass any and all JNK inhibitors.

(4) Guidance of the Specification: The guidance of the specification as to the method of determining whether is compound inhibits JNK protein kinase is not given.

(5) The Predictability or Unpredictability of the Art: The invention is directed to the inhibition of JNK. One of ordinary skill in the art does not know how to predict whether a given compound will inhibit JNK.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to determine or predict whether a compound will inhibit JNK.

(7) Working Examples: The specification is limited to only compounds of formula I for the inhibition of JNK.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for inhibitors of JNK not of formula I. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 22, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "JNK inhibitor" is indefinite for failing to distinctly point out the metes and bounds of the term in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-2, 5, 9 are rejected under 35 U.S.C. 103(a) as being obvious over Bhagwat et al. (WO 02/10137 A2, of record) in view of Hale et al. (US Patent 6,949,580 B2).

The instant claims are directed to a method of treating MD in a patient by administering a compound of formula I.

Bhagwat et al. teach that indazole derivatives of formula I inhibit JNK, a protein kinase (abstract). A preferred compound is 1-(5-(1H-1,2,4-triazol-5-yl)(1H-indazol-3-yl))-3-(2-piperidylethoxy)benzene (example 243, pg. 219).

However, Bhagwat et al. fail to disclose the nexus between protein kinase inhibitors and macular degeneration.

Hale et al. teach that protein kinase inhibitors (col. 1, lines 16-21) are useful for treating ocular diseases such as macular degeneration (col. 21, lines 41-43).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have treated a patient suffering from macular degeneration by administering 1-(5-(1H-1,2,4-triazol-5-yl)(1H-indazol-3-yl))-3-(2-piperidylethoxy)benzene.

A person of ordinary skill in the art would have been motivated to have treated a patient suffering from macular degeneration by administering 1-(5-(1H-1,2,4-triazol-5-yl)(1H-indazol-3-yl))-3-(2-piperidylethoxy)benzene because: (1) Bhagwat et al. discloses 1-(5-(1H-1,2,4-triazol-5-yl)(1H-indazol-3-yl))-3-(2-piperidylethoxy)benzene to be a protein kinase inhibitor and (2) Hale et al. discloses protein kinase inhibitors to be useful for treating macular degeneration. Therefore, a person of ordinary skill in the art would have had a reasonable expectation of success in treating macular degeneration in a patient by administering 1-(5-(1H-1,2,4-triazol-5-yl)(1H-indazol-3-yl))-3-(2-piperidylethoxy)benzene.

Claim(s) 22-23, 26-34 are rejected under 35 U.S.C. 103(a) as being obvious over Bhagwat et al. (WO 02/10137 A2, of record) and Hale et al. (US Patent 6,949,580 B2) as applied to claims 1-2, 5, 9 in view of Ron et al. (US Patent 6,204,270 B1) and Applicant's admission of the prior art.

The instant claims are directed to a method of treating MD in a patient by administering a compound of formula I along in conjunction with other forms of therapy as stated in claims 22-23.

Bhagwat and Hale et al. teach as discussed above, however, fail to disclose other forms of therapy as stated in claims 22-23.

Ron et al. discloses treatment of macular degeneration, a TNF-alpha related eye disorder (col. 4, lines 21-26), with TNF-alpha inhibitors, such as pentoxifylline (col. 2, lines 59-60) and thalidomide (col. 3, lines 5-6).

Applicant's admission of the prior art discloses two forms of macular degeneration, wet and dry MD (pg. 1, lines 20-31). Also disclosed are known treatments for MD, which include verteporfin, interferon α, rhuFab (pg. 3-4), laser photocoagulation therapy, and photodynamic therapy (pg. 5, lines 27-28).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have combined the treatment regimens as disclosed by Bhagwat, Hale, Ron, and in Applicant's admission of the prior art for a person suffering from macular degeneration.

A person of ordinary skill in the art would have combined the treatment regimens as disclosed by Bhagwat, Hale, Ron, and in Applicant's admission of the prior art for a person suffering from macular degeneration because: (1) all of the treatment regimens are directed to macular degeneration and (2) for the therapeutically additive effect of each individual active agent. Therefore, a person of ordinary skill in the art would have had a reasonable expectation of success in treating macular degeneration in a patient

by combining the treatment regimens as disclosed by Bhagwat, Hale, Ron, and in Applicant's admission of the prior art.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER